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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,887	01/21/2004	Lev Korzinov	16491-023001	5443

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EXAMINER

MANUEL, GEORGE C

ART UNIT PAPER NUMBER

3762

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/762,887		KORZINOV, LEV	
	Examiner		Art Unit	
	George Manuel		3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 20-27 is/are rejected.
- 7) ☒ Claim(s) 16-19 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/17/04, 12/15/04</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-3, 5-15, 20-27 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Shusterman et al.'094.

Shusterman et al disclose measuring an ECG and determining a beat-to-beat variability comprising monitoring 9 patients with a Holter monitor and identifying atrial fibrillation in the recorded ECG signals. The relevance of the variability comprises characterizing the RR-series using a Karhunen-Loeve Transform (KLT) and generating KLT-coefficients indicative of nonlinear changes in the RR-series.

Regarding claim 6, Shusterman et al teach ambulatory 24-hour Holter ECGs from 48 subjects with recorded life threatening cardiac arrhythmias comprising spontaneous sustained monomorphic ventricular tachycardia were used for validation of the disclosed method.

Regarding claim 11, several types of changes in the ECG series occur, including slow progressive shortening of RR-intervals, abrupt quasi-periodic jumps, and changes in variance precede initiation of an event. Thus, it is inherent the comparing of the

relevance of the variability in the event to a second predetermined amount of relevance to identify the end of the event be lower than the first predetermined amount.

Regarding claims 13 and 23, the KLT is an orthogonal transformation that employs a weighted combination of several basis functions to represent a signal.

Regarding claim 20, it is inherent the variability in heart rate over a series of between 20 and 200 of the recent R to R intervals is disclosed.

Regarding claims 24 and 25, it is inherent that lower end of physiological values are largely irrelevant to atrial fibrillation and upper range of physiological values negatively indicate atrial fibrillation. Shusterman et al teach arrhythmias may vary in severity from those that are mild and require no treatment to those that are catastrophic and life threatening.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Shusterman et al '094 in view of Klein et al '352.

Shusterman et al disclose all of the claimed features except for transmitting the vent to a remote receiver from an ambulatory patient.

Klein et al teach Holter monitors are well known for monitoring electrocardiograms for long periods of time, but these are bulky and are applied externally to the body and interfere with the patient's normal life, making them impractical for long term use. Klein et al further teach, a telemetry system is capable of sequentially transmitting a digital format, to a remote receiver.


One of ordinary skill in the art would have found it obvious to combine the teaching of Klein et al with the device of Shusterman et al because the teaching applies to Holter monitoring as disclosed in the Shusterman et al reference.

Allowable Subject Matter

Claims 16-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is (571) 272-4952.


George Manuel
Primary Examiner
Art Unit: 3762

12/12/05